

Appl. No. : 10/036,342
Filed : December 26, 2001

SUMMARY OF INTERVIEW

Applicants thank Examiner Kolker and Supervisor Andres for the courtesy extended in the telephone interview on March 7, 2006 with Applicants' representatives Marc Morley and Kathleen Mekjian.

Exhibits and/or Demonstrations

None.

Identification of Claims Discussed

Claims 22-30 and 32-34 were discussed.

Identification of Prior Art Discussed

U.S. Publication No. 2003/0100051 (Ruben et al.) was discussed.

Proposed Amendments

In order to advance the case to allowance, Applicants proposed canceling Claim 30 and amending Claims 22-27 to remove element (c), which recites "amino acids 293-507 of the polypeptide of SEQ ID NO:57." Applicants also proposed amending the claims to recite polypeptides having at least 96%, 97%, and 98% amino acid sequence identity to SEQ ID NO:57.

Principal Arguments and Other Matters

The interview participants discussed the issues and rejections set forth in the January 9, 2006 final Office Action.

Results of Interview

The Examiner agreed to reconsider the utility/enablement rejection under 35 U.S.C. §§ 101/112 in view of Applicants' proposed claim amendments. The Examiner also agreed to reconsider the enablement and written description rejections in view of the amendment to recite at least 95% and greater sequence identity and in view of the discussion of Example 14 of the written description training materials. Finally, the Examiner agreed to reconsider the rejection under 35 U.S.C. § 102(e), in view of the already submitted Rule 131 declaration and in view of the additional comments below.

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REMARKS

The claims have been amended as set forth above. Upon entry of the above-described amendments, Claims 22-29 and 32-34 are pending. Applicants have cancelled Claim 30 without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the cancelled claim in this or any other patent application. Claims 22-27 have been amended to remove reference to amino acids 293-507 of the polypeptide of SEQ ID NO:57.

Also, Claims 22-25 have been amended to recite isolated polypeptides having at least 95%, 96%, 97%, and 98% amino acid sequence identity to the polypeptide of SEQ ID NO:57, respectively. Applicants submit that no new matter has been added by the amendments and support for this amendment can be found, for example, on page 67, lines 25-32 (excerpted below), and elsewhere throughout the specification.

Ordinarily, a PRO polypeptide variant will have ... at least about 95% amino acid sequence identity, alternatively at least about 96% amino acid sequence identity, alternatively at least about 97% amino acid sequence identity, alternatively at least about 98% amino acid sequence identity and alternatively at least about 99% amino acid sequence identity to a full-length native sequence PRO polypeptide sequence as disclosed herein, a PRO polypeptide sequence lacking the signal peptide as disclosed herein, an extracellular domain of a PRO polypeptide, with or without the signal peptide, as disclosed herein or any other specifically defined fragment of a full-length PRO polypeptide sequence as disclosed herein.

Applicants gratefully acknowledge the Examiner's finding that the claimed polypeptides are useful as required under 35 U.S.C. §§ 101/112, and the accompanying withdrawal of the rejection of Claims 22-29 and 32-34 under 35 U.S.C. § 101/112. Applicants also acknowledge the Examiner's withdrawal of the objection to the Oath.

Applicants respond below to the specific rejections raised by the Examiner in the Office Action mailed January 9, 2006. For the reasons set forth below, Applicants respectfully traverse.

Rejection under 35 U.S.C. § 101 - Utility

The Examiner has maintained the rejection of Claim 30 under 35 U.S.C. § 101, as allegedly not being supported by either a specific and substantial asserted utility or a well-

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established utility. Solely in the interest of advancing prosecution of the instant case, Applicants have cancelled Claim 30 thereby rendering the Examiner's rejection moot.

Rejection under 35 U.S.C. § 112, first paragraph - Enablement

The Examiner has rejected Claims 22-27 and 33-34 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable a person skilled in the art to make and use the invention. The Examiner states that the specification is enabling for polypeptides having at least 95% amino acid sequence identity to SEQ ID NO:57 (*Office Action* at 3), however, argues that the specification does not enable polypeptides having 80%, 85% or 90% amino acid sequence identity to SEQ ID NO:57. The Examiner maintains that undue experimentation would be required for the skilled artisan to determine whether variants having 80%, 85%, or 90% amino acid sequence identity to SEQ ID NO:57 would be useful in inducing mesangial cell proliferation.

While Applicants maintain that the specification is enabling for polypeptides having at least 80% amino acid sequence identity to SEQ ID NO:57, solely in the interest of advancing prosecution of the case, Applicants have amended Claims 22-27 to recite polypeptides that have at least 95%, 96%, 97%, or 98% amino acid sequence identity to SEQ ID NO:57. Since the Examiner acknowledges that "it is within the skill of the artisan to make variant polypeptides and test for their ability to induce mesangial cell proliferation, wherein the variants are at least 95% identical to SEQ ID NO:57," (*Office Action* at 3), Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph accordingly.

Rejection Under 35 U.S.C. § 112, first paragraph - Written Description

The Examiner has maintained the rejection of Claims 22-27, 30 and 32-34 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 22-26 refer to a genus of polypeptides having a specified percent amino acid identity to SEQ ID NO:57. In the Office Action, the Examiner maintains that Applicants have only disclosed one

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member of the claimed genus of polypeptides and that neither the art nor the specification discloses a representative number of species falling within the genus. Further, the Examiner asserts that Applicants do not identify a particular portion of the claimed polypeptides that must be conserved. As such, the Examiner maintained that the claims are not adequately described.

The Examiner has also maintained the rejection of Claims 22-27, 30, and 32-34 under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. Specifically, the Examiner notes that Applicants amended the claims to remove the phrase "wherein the extracellular domain is," but that the claims still recite specific fragments of the protein. The Examiner maintains that since the specification and drawings do not specify amino acids 293-507 as recited in the claims, the identification of that region is new matter. For the reasons set forth below, Applicants respectfully disagree.

The well-established test for sufficiency of support under the written description requirement of 35 U.S.C. § 112, first paragraph is whether the disclosure "reasonably conveys to artisan that the inventor had possession at that time of the later claimed subject matter." *In re Kaslow*, 707 F.2d 1366, 1375, 2121 USPQ 1089, 1096 (Fed. Cir. 1983); *see also Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. *See e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. *Union Oil v. Atlantic Richfield Co.*, 208 F.3d 989, 996 (Fed. Cir. 2000).

As discussed during the interview on March 7, 2006, Applicants have amended Claims 22-26 to recite at least 95%, 96%, 97%, 98%, or 99% sequence identity to several polypeptides related to SEQ ID NO:57. The polypeptide variants must also satisfy the limitation "wherein said isolated polypeptide has the ability to induce mesangial cell proliferation." Applicants maintain that the amended claims recite sufficient distinguishing characteristics for the claimed genus of polypeptides. Based upon the detailed description of the cloning and expression of variants of PRO4380 in the specification, the description of the assay in Example 41 (mesangial cell proliferation assay), the actual reduction to practice of SEQ ID NOs:56 and 57, and the

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functional recitation in the instant claims, Applicants submit that one of skill in the art would know that Applicants possessed the invention as claimed in the instant claims.

Furthermore, Applicants submit that the pending claims are analogous to and fully consistent with the claims discussed in Example 14 of the written description training materials. For reasons similar to those expressed in Example 14 of the training materials, the written description requirement should be deemed satisfied for the instant claims. A copy of Example 14 from the training materials is included herewith as Exhibit 1 for the convenience of the Examiner. In Example 14, the written description requirement was found to be satisfied for claims relating to polypeptides having a percentage of homology (95%) to a particular sequence and possessing a particular catalytic activity. The claims were considered fully described even though the applicant had not made any variants and even though only a single representative species was disclosed. Example 14 notes that the procedures for making variants were conventional in the art and that an assay was described in the specification which will identify other proteins having the claimed catalytic activity.

Similarly, in the instant case the pending claims recite a genus of proteins without substantial variation, since the claims require a high percentage of sequence identity to the disclosed sequence of SEQ ID NO:57, and require that the variant sequences have a specific functional activity, namely, the ability to induce mesangial cell proliferation. Also, the specification describes how to make the claimed percentage variants of SEQ ID NO:57. In addition, the specification discloses how to test to determine if a polypeptide has the ability to induce mesangial cell proliferation. Thus, like Example 14, one of skill in the art would conclude that Applicants "were in possession of the necessary common attributes possessed by members of the genus." Therefore, Applicants assert that Claims 22-26 satisfy the written description requirement of § 112, and respectfully request that the Examiner reconsider and withdraw the rejection.

Regarding the new matter rejection of Claims 22-27, 30, and 32-34 under 35 U.S.C. § 112, first paragraph, Applicants maintain that the specification, including Figure 26, refers to specific regions of the protein, including a putative membrane spanning domain comprising amino acids 273-292. Accordingly, it is Applicants' position that the specification also implicitly refers to amino acids 1-272 and 293-507. Nevertheless, as agreed upon in the interview held on

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March 7, 2006, in the interest of advancing prosecution of the instant case Applicants have cancelled Claim 30, and have amended Claims 22-26 to remove reference to amino acids 293-507.

Applicants again thank the Examiner for agreeing to reconsider the written description rejection in view of the above-submitted arguments and amendments. In view of the above, Applicants respectfully request reconsideration and withdrawal of the written description rejections of Claims 22-27 and 32-34 under 35 U.S.C. § 112, first paragraph.

Claim Rejections - 35 U.S.C. § 102(e)

The Examiner has maintained the rejection of Claims 22-27, 29-30, and 33-34 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Publication No. 2003/0100051 (Ruben et al.), published on May 29, 2003, and with an effective date of November 10, 1999. According to the Examiner, Ruben et al. disclose an amino acid sequence that is 97% identical to SEQ ID NO:57. The Examiner acknowledges that the 1.131 declaration is sufficient to overcome the rejection of Claims 28 and 32, but asserts that the declaration is ineffective to overcome the rejection of Claims 22-27, 29-30 and 33-34. The Examiner argues that Applicants Declaration under 37 C.F.R. § 1.131, which demonstrates that Applicants were in possession of the sequence of SEQ ID NO:57 before the effective date of Ruben et al., is not commensurate in scope with claimed subject matter. Applicants respectfully disagree.

As set forth in M.P.E.P. § 715.02, "a reference or activity applied against generic claims may ... be antedated as to such claims by an affidavit or declaration under 37 CFR 1.131 showing completion of the invention of only a single species, within the genus, prior to the effective date of the reference or activity." M.P.E.P. § 715.02 and *See Ex parte Biesecker*, 144 USPQ 129 (Bd. App. 1964). Also, "an affidavit or declaration under 37 CFR 1.131 is required to show no more than the reference shows." M.P.E.P. § 715.02 and *In re Stryker*, 435 F.2d 1340, 168 USPQ 372 (CCPA 1971). Further, a 37 CFR 1.131 affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. *See* M.P.E.P. § 715.02. If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed

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is shown in the reference or activity, the affidavit or declaration is sufficient, whether or not it is a showing of the identical disclosure of the reference or the identical subject matter involved in the activity. *See In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Applicants maintain that the previously submitted declaration was sufficient to overcome the rejection of all of the claims. The declaration establishes that the claimed invention was conceived and diligently reduced to practice prior to November 10, 1999. Applicants maintain that the declaration establish that Applicants were in possession of the full length sequence of SEQ ID NO:57 and its functional activity. *See*, Decl. ¶¶7, 8. As such, Applicants were in possession of the claimed genus of polypeptides, *i.e.* polypeptides having 95% amino acid sequence identity to SEQ ID NO:57 that induce mesangial cell proliferation. Also, the declaration shows that Applicants were in possession of as at least as much of the claimed subject matter as shown in the later published reference. Therefore, Applicants again assert that the declaration is sufficient to overcome the rejection in view of Ruben et al.

Furthermore, Applicants' disclosure in U.S. Provisional Patent Application No. 60/130,359, filed April 4, 1999, to which the instant application claimed priority, demonstrates that Applicants were in possession of the claimed invention prior to November 10, 1999. The provisional application discloses polypeptide variants of PRO4380, including variants having at least 95% identity to PRO4380. As one example:

In another aspect, the invention concerns an isolated PRO4380 polypeptide, comprising an amino acid sequence having at least about 80% sequence identity, preferably at least about 85% sequence identity, more preferably at least about 90% sequence identity, most preferably at least about 95% sequence identity to the sequence of amino acid residues 27 to about 507, inclusive of Figure 1 (SEQ ID NO:1).

Applicants submit that the declaration under 37 C.F.R. § 1.131 and U.S. Provisional Patent Application No. 60/130,359 establishes that Applicants were in possession of the claimed invention prior to the effective date of Ruben et al. Applicants therefore respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102(e).

CONCLUSION

The present application is believed to be in condition for allowance, and an early action to that effect is respectfully solicited. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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